NOV - 4 2004

Summary of Safety and Effectiveness

Submitter:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Karen Cain Manager, Corporate Regulatory Affairs Telephone: (574) 372-4219 Fax: (574) 372-4605
Date:	October 5, 2004
Trade Name:	*VerSys*® Beaded MidCoat Low Head Center Hip Prosthesis
Common Name:	Total hip prosthesis
Classification Name and Reference:	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis 21 CFR § 888.3358
Predicate Device:	*VerSys* Hip System Beaded Hip Prosthesis, manufactured by Zimmer, K973714, cleared December 24, 1997
Device Description:	Like its predicate, the *VerSys* Beaded MidCoat Low Head Center Hip Prosthesis is an straight, modular femoral stem manufactured from Co-Cr-Mo alloy and has a sintered Co-Cr-Mo alloy bead porous surface coating. The prosthesis features a 12/14 Morse-type proximal neck taper to mate with the corresponding 12/14 bore of a femoral head component. Proximal body geometry of the prosthesis is trapezoidal.
Intended Use:	The *VerSys* Beaded MidCoat Low Head Center Hip Prosthesis is designed to achieve biologic fixation to bone and is indicated for:

	Total hip replacement for the following: severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head, nonunion of previous fractures of the femur; congenital hip dysplasia, protrusio acetabuli, slipped capital femoral epiphysis, disability due to previous fusion, previously failed endoprostheses and/or total hip components in the affected extremity, and acute femoral neck fractures. Hemi-hip replacement for the following: fracture dislocation of the hip, elderly, debilitated patients when a total hip replacement is contraindicated, irreducible fractures in which adequate fixation cannot be obtained, certain high subcapital fractures and comminuted fractures, secondary avascular necrosis of the femoral head, pathological fractures of the femoral neck, and osteoarthritis in which the femoral head is primarily affected.
Comparison to Predicate Device:	The modifications to the *VerSys* Hip System Beaded Hip Prosthesis change neither the intended use nor the fundamental scientific technology of the device. Both devices are packaged and sterilized using the same materials and processes.
Performance Data	Non-clinical performance testing demonstrated that the device is equivalent to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 4 2004

Ms. Karen Cain
Manager, Corporate Regulatory Affairs
Zimmer, Inc.
P.O. Box 708
Warsaw, Indiana 46581

Re: K042776
Trade/Device Name: VerSys® Beaded MidCoat Low Head Center Hip Prothesis
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prostheses.
Regulatory Class: II
Product Code: LPH
Dated: October 5, 2004
Received: October 6, 2004

Dear Ms. Cain:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

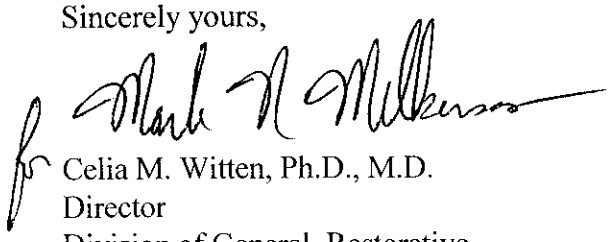
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name:

VerSys® Beaded MidCoat Low Head Center Hip Prosthesis

Indications for Use:

The *VerSys* Beaded MidCoat Low Head Center Hip Prosthesis is designed to achieve biologic fixation to bone and is indicated for:

Total hip replacement for the following: severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head, nonunion of previous fractures of the femur; congenital hip dysplasia, protrusio acetabuli, slipped capital femoral epiphysis, disability due to previous fusion, previously failed endoprostheses and/or total hip components in the affected extremity, and acute femoral neck fractures.

Hemi-hip replacement for the following: fracture dislocation of the hip, elderly, debilitated patients when a total hip replacement is contraindicated, irreducible fractures in which adequate fixation cannot be obtained, certain high subcapital fractures and comminuted fractures, secondary avascular necrosis of the femoral head, pathological fractures of the femoral neck, and osteoarthritis in which the femoral head is primarily affected.

Prescription Use _X_ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(Please do not write below this line - Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhern

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K042776